

**UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK**

Purdue Pharma L.P., et al.

Chapter 11

PURDUE PHARMA L.P., P.F. LABORATORIES, INC.,

PURDUE PHARMACEUTICALS L.P.,

Case No. 19-23649 (RDD)

PURDUE PHARMA TECHNOLOGIES, INC.,

and RHODES TECHNOLOGIES,

DEFENDANTS

AMANDA MORALES

PLANTIFF

FILED
U.S. BANKRUPTCY COURT
2024 JUN 24 PM 1:44
S.D. OF N.Y.

INTRODUCTION

Despite knowing that the long-term use of opioids for chronic pain treatment could lead to injury or death, these entities and individuals took steps to expand the market for their pills into areas of treatment that they knew to be unsafe. To do so, among many other things, the entities and individuals misrepresented the safety and efficacy of their drugs in marketing materials and in communications to healthcare professionals. They paid prominent doctors, advocacy groups, and professional associations vast sums of money to promote the use of opioids in areas that were not medically responsible. These efforts to expand the opioid market were fabulously successful.

Despite the fact that there were no material changes in the circumstances under which opioids were medically indicated, the sales of opioids increased dramatically. In 2007, Purdue Pharma,

L.P (“Purdue”) pleaded guilty to criminal misbranding in connection with its misleading marketing campaign for OxyContin. After the guilty plea Purdue dramatically increased OxyContin sales to the benefit of , Purdue, and the Sackler family, the wealthy family that has owned and operated Purdue for decades. Purdue sought to “supercharge” OxyContin sales by evading the requirements of a “Corporate Integrity Agreement” that Purdue entered as part of its guilty plea. The Sacklers in their plan to inflate, temporarily, the value of Purdue so that the company could be sold. The Sacklers needed to sell a lot of OxyContin quickly, to “turbocharge” OxyContin sales—and then sell the company based on a valuation reflecting those sales, without engaging (or appearing to engage) in the same type of criminal conduct that had led to its guilty plea. Purdue Pharmas negligence for failure to warn about interactions between OxyContin and antidepressants caused my father’s death in 2010. Purdue Pharmas changed the warning label in 2016. The new black box warning emphasized caution of taking OxyContin and antidepressants.

JURISDICTION AND VENUE

This Court has jurisdiction over this action pursuant to New York Constitution, article VI, § 7(a) and CPLR 301 and 302. Judge Robert D Drain stated in an order that this court may hear the merits of my case at a later date when he dismissed the summary judgment for my claims “without prejudice” on 8/16/2021.prior to any approval of a confirmation plan.

PARTIES

Plaintiff Amanda Morales resident of Bernalillo, New Mexico. She's the only child of Ezzard Morales who died in 2010 from the combination of OxyContin and antidepressants. Address 205 Calle Del Banco Bernalillo, NM 87094.

Respondents (appellants and cross-appellees below) are Purdue Pharma, L.P., Purdue Pharma Inc., Purdue Transdermal Technologies L.P., Purdue Pharma Manufacturing L.P., Purdue Pharmaceuticals L.P., Imbrium Therapeutics L.P., Adlon Therapeutics L.P., Greenfield BioVentures L.P., Seven Seas Hill Corp., Ophir Green Corp., Purdue Pharma of Puerto Rico, Avrio Health L.P., Purdue Pharmaceutical Products L.P., Purdue Neuroscience Company, Nayatt Cove Lifescience Inc., Button Land L.P., Rhodes Associates L.P., Paul Land Inc., Quidnick Land L.P., Rhodes Pharmaceuticals L.P., Rhodes Technologies, UDF LP, SVC Pharma LP, SVC Pharma Inc, the Official Committee of Unsecured Creditors of Purdue Pharma L.P., et al., the Ad Hoc Committee of Governmental and Other Contingent Litigation Claimants, the Raymond Sackler Family, the Ad Hoc Group of Individual Victims of Purdue Pharma, L.P., the Multi-State Governmental Entities Group, and the Mortimer-Side Initial Covered Sacklers Persons.

Statement of facts

Corporate Integrity Agreement In May of 2007

1. With effect as of March 1, 2004, MUS entered into a Master Consulting Agreement (the "Agreement") with Purdue Pharma L.P. ("PPLP"). PPLP was the successor to The Purdue Frederick Company, Inc. ("PFC"), which was a New York corporation headquartered in Connecticut. At all relevant times PFC and PPLP were members of a pharmaceutical business enterprise ("Purdue") each member of which was wholly owned directly or indirectly through family trusts and holding companies, 50% by the

family of Mortimer D. Sackler, M.D. and 50% by the family of Raymond R Sackler, M.D. (the “Sacklers”).

2. The Corporate Integrity Agreement In May of 2007, PFC pleaded guilty to federal charges for misleading regulators, doctors, and the public regarding Purdue's opioid OxyContin. In pleading guilty, PFC admitted to falsely marketing OxyContin as a less addictive, safer alternative to other pain medications
3. Pursuant to its Plea Agreement with the United States, PFC agreed to pay a fine of over \$600 million, and PPLP entered into a Corporate Integrity Agreement (“CIA”) with the U.S. Department of Health and Human Services Office of Inspector General.
4. Under the CIA, for five years, Purdue was required to refrain from making any deceptive or misleading claims about OxyContin and was obligated to submit regular compliance reports regarding its sales and marketing practices. Purdue was also required to monitor, report, and attempt to prevent inappropriate prescribing practices.

2010 Death of Ezzard Morales OxyContin and antidepressants interaction resulted in death. No warning was on the label

5. Purdue Pharma failed to warn physicians and patients about the dangerous interaction between OxyContin and antidepressants at the time of my father's death in 2010 and this combination caused serotonin syndrome and was fatal.
6. Six years after his death in 2016 the warning label was changed to include a warning about risks and dangers associated between the interaction of OxyContin and antidepressants which results in serotonin syndrome and was fatal for my father. Purdue Pharma failed to warn at the time of his death and the fact that this warning was black boxed six years later shows it was a major risk and concern to be added to the warning label in bold to emphasized on the warning label.

7. My father Ezzard Morales died in 2010 from taking OxyContin and antidepressants which resulted in serotonin syndrome and he died. My father died when I was 16 years old leaving me without his emotional and financial care and support.
8. At the time of his death there was no warning about serotonin syndrome or the interactions of OxyContin and antidepressants on the warning label.

2016 New warning label states "Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of OxyContin"

9. 2016 OxyContin changed the warning label to include the warning about interactions of OxyContin and antidepressants on the new black boxed warning label
10. Purdue Pharma failed to warn about this dangerous risk and in 2016 the FDA safety announcement explained the risks of opioids and antidepressants with a specific list of antidepressants to avoid taking because it can result in serotonin syndrome. The medications responsible for my father's death are listed on his death certificate and autopsy as OxyContin, amitriptyline, citalopram and tramadol. ALL of these medications were specially listed on the FDA safety announcement as medications not to take with OxyContin.
11. The FDA safety announcement stated that from January 1, 1969 there have been 43 reported cases of serotonin syndrome involving opioids combined with antidepressants so Purdue Pharma knew or should have known about this risk and danger.
12. Serotonin syndrome is a serious drug reaction. It is caused by medications that build up high levels of serotonin in the body. Serotonin is a chemical that the body produces naturally. It's needed for the nerve cells and brain to function. But too much serotonin

**causes signs and symptoms that can range from shivering, diarrhea, mental changes
paranoia, anxiety, hallucinations and confusion.**

13. There aren't any tests to diagnose serotonin symptoms. Your healthcare provider usually makes the diagnosis based on the results of your physical exam, review of your symptoms and history of medications you take that affect serotonin levels. It is diagnosed clinically using the The Hunter Serotonin Toxicity Criteria Requirement – in the presence of a serotonergic agent:

Signs and symptoms include:

- **Agitation or restlessness**
- **Insomnia**
- **Confusion**
- **Rapid heart rate and high blood pressure**
- **Dilated pupils**
- **Loss of muscle coordination or twitching muscles**
- **High blood pressure**
- **Muscle rigidity**
- **Heavy sweating**
- **Diarrhea**
- **Headache**
- **Shivering**
- **Goose bumps**

Severe serotonin syndrome can be life-threatening. Signs include:

- **High fever**
- **Tremor**
- **Seizures**
- **Irregular heartbeat**
- **Unconsciousness**

14. This syndrome was first described in the literature during the 1960s in studies of single and combination therapy with antidepressant medications.¹ Potential mechanisms of serotonin syndrome include increased serotonin synthesis or release; reduced serotonin uptake or metabolism; and direct serotonin receptor activation.

15. A study based in general practice reported the incidence of serotonin syndrome at 0.5–0.9 cases per 1000 patient-months of treatment. This is likely to be an underestimate as it pertains to patients on monotherapy with selective serotonin reuptake inhibitors (SSRIs); this rises to 15% where overdose with serotonergic medication has occurred (Reference Isbister, Buckley and Whyte Isbister 2007).
16. Autopsy report states that my father was restless, paranoid and confused and was put back in bed and later found unconscious. He had diarrhea but due to his GI problems this wasn't anything out of the ordinary that we believed was a red flag.
17. My dad died at his home and his family thought he didn't get good sleep and was sleep deprived and that's why he was restless, confused and paranoid with anxiety and that is why he was put back in bed we didn't know these were symptoms of serotonin syndrome. He had a rapid heart beat but again we thought that was due to his anxiety and we recommended he relax and get some rest and get some sleep.
18. Autopsy report states that his prescription medications OxyContin, amitriptyline, citalopram and tramadol intoxication were the cause of death.
19. My father suffered depression and anxiety and took antidepressants the majority of his adult life. His depression stemmed from the death of his mother at 8 years old when she died of breast cancer and he had a void in his life.
20. Opioids interact with antidepressants and it wasn't until 2016 that the FDA required all opioids to include a warning to caution about the dangers of opioids and antidepressants and can cause serotonin syndrome and be fatal.
21. Key findings. Eleven percent of Americans aged 12 years and over take antidepressant medication. The federal government's health statisticians figure that about one in every 10 Americans takes an antidepressant. Purdue should have warned about OxyContin interacting with antidepressants.

Claims have been dismissed without prejudice by judge Robert D Drain “to be heard on the merits” of my case “at a later date” prior to any confirmation plan approval

22. Purdue Pharma has taken steps to avoid accountability and have no intention of resolving this issue. Hearing for summary judgement for these claims was on 8/16/2021 and was dismissed without prejudice. Judge Robert Drain stated that my case could be heard over the merits of my case at a later date. See attached order.

23. Purdue pharma is responsible for my father’s death and their negligence maximized their profit and sale of OxyContin.

24. I should be allowed just like anyone else the opportunity to seek justice because I just want to be heard and denying me at least the chance for justice would be a great injustice because it’s unfair to group my claims with other claimants that are related to addiction when my claims are not related to addiction or abatement.

25. There have been no consequences for the Sachklers and they are still very wealthy and enjoy freedom comfortably and not allowing me to be heard only sets a precedent that this kind of egregious behavior can be done and accountability avoided. My intention isn’t to be selfish and I understand there’s other claimants I just want closure and to peacefully move on and just want to be acknowledged because my life was forever changed at 16 when my father died. My father’s death could have been avoided and it caused me a tremendous amount of pain and hundreds of hours in therapy for the traumatic experience of losing my dad at such a difficult age being a teenager who needed my dad for love, guidance, protection and to financially provide for me.

Purdue 's plan to avoid accountability

26. The Sacklers Seek to Divert Money to Themselves. The Sackler family is among the richest families in the United States. Members of the Sackler family have controlled Purdue at all times relevant to this complaint, not merely as the sole owners, but also as members of the board and as executive officers and agents.
27. Following the guilty plea, the Sacklers sought to insulate themselves from the risk they perceived in the continued operation of the Purdue business of selling opioids. Ten days after the guilty plea was announced, David Sackler wrote to his father, Richard Sackler, and uncle, Jonathan Sackler, concerning the risk the family now faced: legal liability for selling OxyContin. Although Jonathan Sackler asserted that there was no basis to sue members of the family, David asserted otherwise, writing: "We will be sued. Read the op-ed stuff in these local papers and ask yourself how long it will take these lawyers to figure out that we might settle with them if they can freeze our assets and threaten us."
28. On April 18, 2008, Richard Sackler, then the co-chairman of the board along with his uncle, communicated to other family members that Purdue's business of selling OxyContin and other opioids was "a dangerous concentration of risk." One option to address this risk was to sell the company to, or merge the company with, another pharmaceutical manufacturer. The proceeds of such a transaction could then be reinvested in diversified assets, thereby achieving the Sacklers' desired insulation from liability for the ongoing opioid business.
29. Another option was to have Purdue borrow money in order to assure Purdue had adequate funds to continue operating while the Sacklers, as owners, should "distribute more free cash flow" to themselves. This would have the effect of maximizing the amount of money they, as owners, could extract from the business and invest elsewhere. In order to pursue either of these options, the Sacklers needed to maximize opioid sales in the short term so as to make Purdue—by then the subject of substantial public scrutiny—appear either as an attractive acquisition target or merger partner to another pharmaceutical manufacturer or as a creditworthy borrower to a lender. In short, the

Sacklers planned to engage in a final flurry of opioid pushing in order to cash themselves out of their pharmaceutical business.

30. In the 2020 Settlement Agreement, Purdue pleaded guilty to defrauding health agencies, violating anti-kickback laws, paying illegal kickbacks to doctors, and “using aggressive marketing tactics to convince doctors to unnecessarily prescribe opioids—frivolous prescriptions that experts say helped fuel a drug addiction crisis that has ravaged America for decades.”
31. Purdue Pharma L.P. announced the introduction of the Medical Education Resource Catalog Online (MERCOnline), a web-based resource that provides licensed healthcare professionals in the U.S. with access to free educational materials to help improve the care of people with pain. The resources address important aspects of pain management including patient and peer communication, medication therapy management, risk management, and safe storage and disposal of medication. The *Focused and Customized Education Topic Selections in Pain Management* (FACETS), is a CD ROM that contains various learning modules and resources that are developed for clinical educators and healthcare professionals interested in pain management education. Some topics within FACETS include: *Pain Care in the Older Adult* and *Medication Errors and Strategies to Improve Safety and Outcomes with Analgesics*.
32. These strategies are both extensive and comprehensive, involving webs or networks of relationships with government, the academy, and civil society (Marks 2019a). Although relationships are widespread at institutional levels, media attention tends to focus on individuals—most commonly, excoriating doctors and researchers for failing to disclose that they have industry-related financial conflicts of interest.
33. When Richard Sackler was president of Purdue Pharma in 2001, he urged colleagues to blame and “hammer” patients, describing them contemptuously as “abusers,” “culprits,” and “reckless criminals” (Zezima and Bernstein 2019).

34. Purdue Pharma promoted Oxycobtin by building webs of relationships with a variety of public health agencies, academic institutions, and public health NGOs, as well as thousands of individual health professionals.

35. During 2009 and 2010 at the peak of the most OxyContin sales physicians wrote more than seventy opioid prescriptions per year for every hundred Americans.

OxyContin has inadequate information in 2010 regarding safety

36. No one but Purdue Pharma is responsible for my father's death because it wasn't an issue of misuse or addiction. His doctor relied on information Purdue Pharma shared with the FDA and relied on the warning label and other information provided at the time of his death.

37. Without knowledge of the dangers and risks the public and the medical community trusted and relied on the information available and had no reason to know or suspect the adverse reaction of OxyContin combined with antidepressants would result in serotonin syndrome and be fatal.

38. Opioids and antidepressants can cause serotonin syndrome and as the FDA safety announcement stated in 2016 when the warning was changed and stated that serotonin syndrome from combinations of opioids and antidepressants has been known since January 1, 1969 and is not a new piece of information that was recently discovered, it has only been recently communicated by Purdue Pharma but not recently discovered.

Death of a parent as a minor

39. I was 16 when my dad unexpectedly died and he was 37 years old. I suffered severe depression and anxiety.

40. I was graduating high school a year early and my dad was proud and ready to help me with college. After his death I didn't have any academic achievements in college and I struggled mentally and financially and didn't stay in school.

41. I spent a lot of time in therapy and my teenage years were rough for me. I didn't enjoy the things I should have at that age and became depressed and had anxiety really bad. I was not very social and I found life to be exhausting and overwhelming.

42. My dad and I were close, I am an only child. My mom went into labor with me on my dad's 21st birthday and the next day I was born so birthdays are always difficult.
43. My father's death left a void in my life and I had no one to protect me, love me or give me advice the way my dad did and I felt very lonely.
44. My dad wasn't there when I graduated high school, when I got my first job or walk me down the aisle when I got married. I had no one but my mom and it's milestones that remind me of the things I will never get to share or experience with my dad.

CAUSES OF ACTION
FIRST CAUSE OF ACTION
DECEPTIVE ACTS AND PRACTICES
New York General Business Law § 349

45. Plaintiffs incorporate the allegations of all prior paragraphs within this Complaint as if they were fully set forth herein.

Defendants' acts were consumer oriented.

46. Defendants' acts and/or practices are "deceptive or misleading in a material way" and include but are not limited to:
- a. misrepresenting the truth about how opioids safety
 - b. misrepresenting that opioids improve function;
 - c. misrepresenting that risk associated with OxyContin and antidepressants
 - d. falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment. Defendants' acts and/or practices caused actual harm to the Plaintiff.

47. Plaintiff has been injured as a result of Defendant's acts and/or practices.

48. New York General Business Law § 349 declares unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in the state, and allows any person who has been injured by reason of any violation of that statute to bring an action to recover actual damages.

49. Defendants violated New York General Business Law § 349, because they engaged in false advertising in the conduct of a business, trade or commerce in this state.

50. Defendants violated New York General Business Law § 349, because they engaged in false advertising in the conduct of a business, trade or commerce in this state.

51. Plaintiffs are entitled to recover their damages caused by Defendants' the violation of New York General Business Law § 349 in an amount to be determined at trial.

SECOND CAUSE OF ACTION
FALSE ADVERTISING
New York General Business Law §350

52. Plaintiffs incorporate the allegations of all prior paragraphs within this Complaint as if they were fully set forth herein.

53. Defendants violated New York General Business Law § 350, because they engaged in false advertising in the conduct of a business, trade or commerce in this state.

54. Defendants' acts were consumer oriented and triggered reliance by patients, physicians and others.

55. Defendants' acts and/or practices are "deceptive or misleading in a material way" and include but are not limited to:

- a. misrepresenting that opioids improve function;
- b. misrepresenting that increased doses pose no significant additional risks;
- c. falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

56. Defendants' acts and/or practices caused actual harm to Plaintiffs.

57. Plaintiffs have been injured as a result of Defendants' acts and/or practices.

58. Plaintiffs has been injured by reason of Defendants' violation of § 350.

59. Plaintiffs are entitled to recover its damages caused by Defendants' violation of New York General Business Law § 350 in an amount to be determined at trial.

THIRD CAUSE OF ACTION
NEGLIGENCE

60. Plaintiffs incorporate the allegations of all prior paragraphs within this Complaint as if they were fully set forth herein.

61. Purdue, owed a duty of care to Plaintiffs, pursuant to which it would not encourage the over-marketing and over-prescribing of a controlled substance known at the time to be addictive and known at the time to be a threat to public health.

62. Purdue was implementing a sales and marketing campaign, including Project Turbocharge, that would dramatically increase the amount of OxyContin prescribed and distributed to the Plaintiffs' citizens. In the process, Purdue continually devised misleading claims regarding OxyContin as part of their efforts to get health care providers to write more and more OxyContin prescriptions.

63. As a direct and proximate result of Purdue's negligent conduct, Plaintiff has suffered and will continue to suffer harm.

64. Plaintiff is entitled to recover their damages caused by Defendants' negligence in an amount to be determined at trial.

Fourth CAUSE OF ACTION FAILURE TO WARN

65. Plaintiffs incorporate the allegations of all prior paragraphs within this Complaint as if they were fully set forth herein.

66. Purdue, owed a duty of care to Plaintiffs, pursuant to which Purdue Pharma was required to follow FDA standards regarding transparency and safety.

67. The FDA safety announcement stated that serotonin syndrome has been known since January 1, 1969 so Purdue Pharma knew or should have known the dangers but failed to warn people until 2016.

68. As a direct and proximate result of Purdue's failure to warn Plaintiff has suffered and will continue to suffer harm.

69. Plaintiffs are entitled to recover their damages caused by Defendants' negligence in an amount to be determined at trial.

Fifth CAUSE OF ACTION

FRAUD (ACTUAL AND CONSTRUCTIVE) AND DECEIT

70. Plaintiff incorporate the allegations of all prior paragraphs within this Complaint as if they were fully set forth herein.

71. Purdue made and caused to be made false representations to healthcare providers working in Plaintiffs' communities and/or omitted material facts, regarding the risks, efficacy, and medical necessity of opioids, generally, and Purdue's opioids, specifically.

Overstated the efficacy of opioids, generally, and Purdue's opioids, specifically, including making false statements regarding the effectiveness of the drugs for treating specific subsets of the patient population

- a. Misrepresented the medical usefulness and necessity of opioids, generally, and Purdue's opioids, specifically, including affirmatively marketing their drugs for off label uses (i.e. osteoarthritis) without solicitation and not in response to questions from healthcare providers.

72. Purdue's misrepresentations and omissions had a tendency to deceive others, to violate public confidence, and/or injure public interests. Purdue having chosen to craft the marketing plan used by Purdue to make representations to healthcare providers regarding their opioids, were under a duty to disclose the whole truth, and not disclose partial and misleading truths.

73. intended healthcare providers throughout the United States, including in the Plaintiffs community to rely upon Purdue's false statements regarding the risks, efficacy, and medical necessity of opioids generally, and Purdue's opioids specifically, in order to increase the number of opioid prescriptions made by healthcare providers.

74. Healthcare providers in Plaintiffs' community did in fact rely on the false representations made in Purdue's marketing plan created by Purdue Pharma

75. Purdue acted with knowledge and willful intent, with reckless disregard for the rights of others, and/or intentionally and with malice towards others.

76. Plaintiff has suffered actual pecuniary loss as a result of fraudulent representations and omissions.

SEVENTH CAUSE OF ACTION UNJUST ENRICHMENT

77. Plaintiff incorporates the allegations of all prior paragraphs within this Complaint as

if they were fully set forth herein.

78. This compensation for increasing the sales of Purdue's deadly products constitutes money in the possession of Purdue that, in equity and good conscience, the sackler family owned and profited and are not in bankruptcy and should not be allowed to avoid accountability .

EIGHTH CAUSE OF ACTION REQUEST FOR DECLARATORY RELIEF UNDER CPLR 3001

79. Plaintiffs incorporate the allegations of all prior paragraphs within this Complaint as if they were fully set forth herein.

80. CPLR 3001 authorizes the Supreme Court to “render a declaratory judgment having the effect of a final judgment as to the rights and other legal relations of the parties to a justiciable controversy.”

81. The Master Agreement for Purdue contains an indemnification provision pursuant to which Purdue agrees to indemnify and hold harmless the sackler family

82. Plaintiffs are claimants in the Purdue bankruptcy. Any claim for indemnity made by the sacklers in the Purdue bankruptcy under the Master Agreement could have the effect of reducing the value of Plaintiffs' claims in the Purdue bankruptcy.

83. Plaintiffs allege in their proofs of claim that their claims arise from Purdue's tortious, deceptive, unreasonable, or otherwise unlawful conduct with respect to the marketing, promotion, sale, and/or distribution of prescription opioid products. They further allege that Purdue acted jointly with others.

84. The doctrine of *in pari delicto* bars the sachklers from being indemnified by, or to receive contribution from Purdue for the wrongdoing alleged herein.

85. Plaintiff is entitled to a declaration that under New York law the sachklers are not entitled to indemnification or contribution from Purdue for any liability arising from the wrongdoing alleged herein.

JURY DEMAND

Plaintiffs request a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray that this Court enter judgment against Defendant as follows:

- A. Awarding Plaintiffs their actual damages for the damages caused by the death of my father when I was a minor including but not limited to (1) costs for providing medical care, funeral and (2) burial of Ezzard Morales, (3) pain and suffering
- B. Awarding Plaintiffs punitive damages; pre-judgment and post-judgment interest; and
- C. Providing all other and further relief as this Court may deem just and proper.

Respectfully submitted

~~12/28/2023~~ dated

1/16/2024

Amanda Morales
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Amanda Morales

2009 warning label no mention of CNS depressants or CYP3A4 inhibitors as a risk when taking OxyContin

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use OXYCONTIN® safely and effectively. See full prescribing information for OXYCONTIN.

OxyContin® (oxycodone hydrochloride controlled-release) Tablets CII
Initial U.S. Approval: 1982

WARNING: IMPORTANCE OF PROPER PATIENT SELECTION AND POTENTIAL FOR ABUSE

See full prescribing information for complete boxed warning.

- OxyContin contains oxycodone which is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine. (9)
- OxyContin is indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. (1)
- OxyContin is NOT intended for use on an as-needed basis. (1)
- OxyContin 60 mg and 80 mg Tablets, a single dose greater than 40 mg, or a total daily dose greater than 80 mg are only for use in opioid-tolerant patients to avoid fatal respiratory depression. (2.7)
- Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids. (2.2)
- OxyContin tablets must be swallowed whole and must not be cut, broken, chewed, crushed, or dissolved which can lead to rapid release and absorption of a potentially fatal dose of oxycodone. (2.1)
- The concomitant use with cytochrome P450 3A4 inhibitors such as macrolide antibiotics and protease inhibitors may result in an increase in oxycodone plasma concentrations and may cause potentially fatal respiratory depression. (7.2)

-----INDICATIONS AND USAGE-----

OxyContin is an opioid agonist indicated for:

- Management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. (1)
- Not for use on an as-needed basis or in the immediate post-operative period. (1)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use OXYCONTIN® safely and effectively. See full prescribing information for OXYCONTIN.

OXYCONTIN® (oxycodone hydrochloride) extended-release tablets, for oral use, CH

Initial U.S. Approval: 1950

WARNING: ADDICTION, ABUSE AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES AND OTHER CNS DEPRESSANTS

See full prescribing information for complete boxed warning.

- which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions. (5.1)
- Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. Instruct patients to swallow OXYCONTIN tablets whole to avoid exposure to a potentially fatal dose of oxycodone. (5.2)
- Accidental ingestion of OXYCONTIN, especially by children, can result in a fatal overdose of oxycodone. (5.2)
- Prolonged use of OXYCONTIN during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available. (5.3)
- Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of oxycodone. (5.4, 7, 12.3)
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation. (5.5, 7)

RECENT MAJOR CHANGES

| | |
|------------------------------|---------|
| Box Warning | 12/2016 |
| Warnings and Precautions (5) | 12/2016 |

INDICATIONS AND USAGE

OXYCONTIN is an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate in:

- Adults; and
- Opioid-tolerant pediatric patients 11 years of age and older who are already receiving and tolerate a minimum daily opioid dose of at least 20 mg oxycodone orally or its equivalent.

Limitations of Use

- Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve OXYCONTIN for use in patients for whom alternative treatment options (e.g. non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient

Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of oxycontin”

2016 recent major changes Warnings and Precautions (5) changes

Death certificate cause of death Drug (oxycodone, amitriptyline, citalopram, tramadol) intoxication

| | | | |
|--|-------------------------------------|--|--|
| METHOD OF DISPOSITION | | New M | |
| Burial | <input type="checkbox"/> Donation | <input type="checkbox"/> Removal from State | |
| Cremation | <input type="checkbox"/> Entombment | <input type="checkbox"/> Other (Specify): <<<>>> | |
| FUNERAL SERVICE FACILITY | | COUNTY OF DEATH | |
| Mexico Mortuary Service | | | |
| PLACE OF DEATH | TYPE OF PLACE | NAME OF PERSON SIGNING | |
| | Decedent's Residence | <<<Ro Signature | |
| <input type="checkbox"/> Natural <input checked="" type="checkbox"/> Accident <input type="checkbox"/> Homicide <input type="checkbox"/> Suicide | | | |
| CAUSE OF DEATH | | | |
| into such as ulcers, injuries, or complications that already existed the death. | | | |
| Drug (oxycodone, amitriptyline, citalopram, tramadol) intoxication | | | |
| <<<>>> | | | |

| | | |
|--|--|----------|
|  |  <div data-bbox="675 352 1026 365"> <p>AUTOPSY REPORT</p>  </div> | <p>4</p> |
|  |  <div data-bbox="675 365 1026 382">  </div> | |

Heart: negative
Lungs: anthracosis; autolysis; edema
Kidney: autolysis
Liver: mild fatty change; chronic non-specific hepatitis
Colon: ischemic changes with bowel wall necrosis and acute inflammation;
mucosal hemorrhage

- I. Acute intoxication by combined action of oxycodone, amitriptyline, citalopram, and tramadol
 - A. Pulmonary congestion and edema
 - B. Agonal aspiration of gastric contents
 - C. Ischemic hemorrhagic colitis
- II. Mild coronary arteriosclerosis
- III. Fatty change of liver
- IV. Chronic non-specific hepatitis
- V. Colonic diverticulosis
- VI. Laceration of face

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Autopsy report OxyContin- Heart Blood adverse reactions combination with central nervous depressant

3. Oxycodone - Free (OxyContin®, Roxicodone®) - Heart Blood:

Oxycodone is a DEA Schedule II controlled semi-synthetic narcotic analgesic. It is used to control pain associated with such ailments as bursitis, injuries, simple fractures and neuralgia. The addiction liability of oxycodone is about the same as for morphine. This compound should be administered in the smallest effective dose and as infrequently as possible. The usual adult dose of the hydrochloride salt is 5 mg every 6 hr.

Following the oral administration of oxycodone as both sustained-release (Oxycontin®) and regular formulations, peak plasma concentrations of the compound are generally less than 100 ng/mL; however, the sustained-release preparation may also result in peak concentrations of oxycodone less than 10 ng/mL serum.

Page 5 of 7

Reference Comments:

Oxymorphone is a pharmacologically active metabolite of oxycodone that may be seen in blood in very low concentrations.

In overdose, oxycodone can produce stupor, coma, muscle flaccidity, severe respiratory depression, hypotension and cardiac arrest. In two oxycodone-related suicides, blood concentrations of 4300 and 14000 ng/mL were reported. However, sustained-release preparations appear to produce adverse reactions, up to including death, at concentrations of oxycodone well less than 1000 ng/mL, especially in combination with central nervous system depressants, depending on use pattern and route of administration.

Next is the FDA safety announcement from 2016. 11 pages long





U.S. Food and Drug Administration
Protecting and Promoting Your Health

Drug Safety Communications

FDA Drug Safety Communication: FDA warns about several safety issues with opioid pain medicines; requires label changes

Safety Announcement

[3-22-2016] The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. We are requiring changes to the labels of all opioid drugs to warn about these risks.

More specifically, the labels will warn about the following:

- Opioids can interact with antidepressants and migraine medicines to cause a serious central nervous system reaction called serotonin syndrome, in which high levels of the chemical serotonin build up in the brain and cause toxicity (see List of Serotonergic Medicines).
- Taking opioids may lead to a rare, but serious condition in which the adrenal glands do not produce adequate amounts of the hormone cortisol. Cortisol helps the body respond to stress.
- Long-term use of opioids may be associated with decreased sex hormone levels and symptoms such as reduced interest in sex, impotence, or infertility.

Opioids are a class of powerful narcotic pain medicines that are used to treat moderate to severe pain that may not respond well to other pain medicines (see List of Opioids). They can help manage pain when other treatments and medicines are not able to provide enough pain relief, but they also have serious risks including misuse and abuse, addiction, overdose, and death.

Recommendations and information for patients and health care professionals

Serotonin syndrome:

Patients taking an opioid along with a serotonergic medicine (see List of Serotonergic Medicines) should seek medical attention immediately if they develop symptoms such as agitation; hallucinations; rapid heart rate; fever; excessive sweating; shivering or shaking; muscle twitching or stiffness; trouble with coordination; and/or nausea, vomiting, or diarrhea. Symptoms generally start within several hours to a few days of taking an opioid with another medicine that increases the effects of serotonin in the brain, but symptoms may occur later, particularly after a dose increase.

Health care professionals should discontinue opioid treatment and/or use of the other medicine if serotonin syndrome is suspected.

Cases of serotonin syndrome in the FDA Adverse Event Reporting System (FAERS) database were reported more frequently with the opioids fentanyl and methadone used at the recommended doses. Therefore, we are requiring a new statement in the *Warnings and Precautions* section to be added to these drug labels. Some opioids, including tramadol, tapentadol, and meperidine, already have warnings about serotonin syndrome. Cases were also reported with other opioids, so the labels of all these drugs will be updated to include information about serotonin syndrome in the *Drug Interactions* and *Adverse Reactions* sections.

Adrenal insufficiency:

Patients should seek medical attention if they experience symptoms of adrenal insufficiency such as nausea, vomiting, loss of appetite, fatigue, weakness, dizziness, or low blood pressure. **Health care professionals** should perform diagnostic testing if adrenal insufficiency is suspected. If diagnosed, treat with corticosteroids and wean the patient off of the opioid, if appropriate. If the opioid can be discontinued, follow-up assessment of adrenal function should be performed to determine if treatment with corticosteroids can be discontinued.

We are requiring a new statement about adrenal insufficiency to be added to the *Warnings and Precautions* section of all opioid labels.

Decreased sex hormone levels:

Patients should inform their health care professionals if they experience symptoms of low libido, impotence, erectile dysfunction, lack of menstruation, or infertility.

Health care professionals should conduct laboratory evaluation in patients presenting with such signs or symptoms.

We reviewed published studies that assessed levels of sex hormones in patients taking opioids chronically;¹⁻²¹ however, all had limitations that make it difficult to determine whether the symptoms were caused by the opioids or other factors. The labels of some opioids already describe this possible risk, and we are now adding consistent information to the *Adverse Reactions* section of all opioid labels.

We urge patients and health care professionals to report side effects involving opioids or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

List of Opioids

| Generic Name | Found in Brand Name(s) |
|----------------|---|
| alfentanil | Alfenta |
| buprenorphine | Belbuca, Bunavail, Buprenex, Butrans, Suboxone, Zubsolv |
| butorphanol | No brand name currently marketed |
| codeine | Fioricet w/ codeine, Fiorinal w/ codeine, Tylenol w/ codeine |
| dihydrocodeine | Synalgos-DC |
| fentanyl | Abstral, Actiq, Duragesic, Fentora, Ionsys, Lazanda, Sublimaze, Subsys |
| hydrocodone | Anexsia, Hysingla ER, Lortab, Norco, Reprexain, Vicodin, Vicoprofen, Zohydro ER |
| hydromorphone | Dilaudid, Dilaudid-HP, Exalgo |
| meperidine | Demerol |
| methadone | Dolophine, Methadose |
| morphine | Astramorph PF, Duramorph PF, Embeda, Infumorph, Kadian, Morphabond, MS Contin |
| oxycodone | Oxaydo, Oxycet, Oxycontin, Percocet, Percodan, Roxicet, Roxicodone, Xartemis XR |
| oxymorphone | Opana, Opana ER |
| pentazocine | Talwin |
| remifentanil | Ultiva |
| sufentanil | Sufenta |
| tapentadol | Nucynta, Nucynta ER |
| tramadol | Conzip, Ultracet, Ultram, Ultram ER |

List of Serotonergic Medicines

| Generic Name | Found in Brand Name(s) |
|---|---|
| Selective Serotonin Reuptake Inhibitors (SSRIs) | |
| paroxetine | Paxil, Paxil CR, Pexeva, Brisdelle |
| fluvoxamine | Luvox, Luvox CR |
| fluoxetine | Prozac, Prozac Weekly, Sarafem, Selfemra, Symbyax |
| sertraline | Zoloft |
| citalopram | Celexa |
| escitalopram | Lexapro |
| Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs) | |
| venlafaxine | Effexor XR |
| desvenlafaxine | Pristiq, Khedezla |
| duloxetine | Cymbalta |
| milnacipran | Savella |
| Tricyclic Antidepressants (TCAs) | |
| amitriptyline | No brand name currently marketed |
| desipramine | Norpramin |
| clomipramine | Anafranil |
| imipramine | Tofranil, Tofranil PM |
| nortriptyline | Pamelor, Aventyl |
| protriptyline | Vivactil |
| doxepin | Zonalon, Silenor |
| trimipramine | Surmontil |
| Monoamine Oxidase Inhibitors (MAOIs) | |
| isocarboxazid | Marplan |
| phenelzine | Nardil |
| selegiline | Emsam, Eldepryl, Zelapar |
| tranylcypromine | Parnate |
| Other Psychiatric Medicines | |
| amoxapine | No brand name currently marketed |
| maprotiline | No brand name currently marketed |
| nefazodone | No brand name currently marketed |
| trazodone | Oleptro |
| buspirone | No brand name currently marketed |
| vilazodone | Viibryd |
| mirtazapine | Remeron, Remeron Soltab |
| lithium | Lithobid |
| Migraine Medicines | |
| almotriptan | Axert |
| frovatriptan | Frova |
| naratriptan | Amerge |

| | |
|-------------------------------------|---|
| rizatriptan | Maxalt, Maxalt-MLT |
| sumatriptan | Imitrex, Imitrex Statdose, Alsuma, Sumavel Dosepro, Zecuity, Treximet |
| zolmitriptan | Zomig, Zomig-ZMT |
| Antiemetics | |
| ondansetron | Zofran, Zofran ODT, Zuplenz |
| granisetron | Kytril, Sancuso |
| dolasetron | Anzemet |
| palonosetron | Aloxi |
| Other Serotonergic Medicines | |
| dextromethorphan | Bromfed-DM, Delsym, Mucinex DM, Nuedexta |
| linezolid | Zyvox |
| cyclobenzaprine | Amrix |
| methylene blue | |
| St. John's wort | |
| tryptophan | |

Facts about Opioids

- Opioids are powerful prescription medicines that can help manage pain when other treatments and medicines are not able to provide enough pain relief (see List of Opioid Medicines). However, opioids also carry serious risks, including of misuse and abuse, addiction, overdose, and death.
- Prescription opioids are divided into two main categories – immediate-release (IR) products, usually intended for use every 4 to 6 hours; and extended release/long acting (ER/LA) products, intended to be taken once or twice a day, depending on the individual product and patient.
- Certain opioids, such as methadone and buprenorphine, can also be prescribed as a form of treatment for opioid addiction.
- Opioids are available in many different formulations, including tablets, capsules, lozenges, sublingual tablets, transdermal patches, nasal sprays, and injections.
- Common side effects of opioids include drowsiness, dizziness, nausea, vomiting, constipation, physical dependence, and slowed or difficult breathing.
- The risk of opioid addiction, abuse or misuse is increased in patients with a personal or family history of substance abuse, or mental illness.
- It is important to lock up opioids and to dispose of them properly to keep them from falling into the wrong hands.

Additional Information for Patients

- FDA is warning about several safety issues with the class of powerful narcotic opioid pain medicines:

- Opioids can interact with certain medicines that increase the effects of serotonin, which is a chemical in the brain. The interacting medicines include antidepressants and migraine medicines, and the interaction causes a serious central nervous system reaction called serotonin syndrome (see List of Serotonergic Medicines).
 - Taking opioids may lead to a rare, but serious condition called adrenal insufficiency in which the adrenal glands do not produce adequate amounts of the steroid hormone, cortisol, particularly during stressful conditions.
 - Long-term use of opioids may be associated with decreased sex hormone levels.
- Inform your health care professional about all the drugs you are taking, including prescription and over-the-counter medicines. It is helpful to keep a list of all your current medicines in your wallet or another location where it can be easily retrieved. You can fill out and print a copy of My Medicine Record.
- If you are taking an opioid pain reliever and don't know if you are also receiving serotonergic medicines or other medicines that interact with opioids, contact your health care professional.
- Opioids are powerful narcotic pain medicines that can help manage pain when other treatments and medicines are not able to provide enough pain relief. However, even when used properly, opioids also carry serious risks, and they can be misused and abused, causing addiction, overdose, and death.
- Seek medical attention immediately if you develop any symptoms of serotonin syndrome such as:
 - Agitation
 - Hallucinations
 - Rapid heart rate
 - Fever
 - Excessive sweating
 - Shivering or shaking
 - Muscle twitching or stiffness
 - Trouble with coordination
 - Nausea, vomiting, or diarrhea
- Also seek medical attention if you experience symptoms of adrenal insufficiency such as:
 - Nausea or vomiting
 - Loss of appetite
 - Fatigue
 - Weakness
 - Dizziness
 - Low blood pressure.
- Inform your health care professional if you experience signs or symptoms of decreased sex hormone levels such as low libido, impotence, erectile dysfunction, lack of menstruation, or infertility.

- Talk to your health care professional if you have any questions or concerns about opioids or other medicines you are taking.
- Read the patient information leaflet or Medication Guide that comes with your filled prescription(s).
- Report side effects from opioids or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Additional Information for Health Care Professionals

- FDA is warning about several safety issues with the class of opioid pain medicines. These include serotonin syndrome, adrenal insufficiency, and androgen deficiency.

Serotonin syndrome

- Serotonin syndrome can occur during concomitant use of opioids with serotonergic drugs. This may occur within the recommended dosage range.
- If concomitant use of an opioid with a serotonergic drug is warranted, carefully observe the patient, particularly during treatment initiation and dose increases.
- Symptoms of serotonin syndrome may include mental status changes such as agitation, hallucinations, or coma; autonomic instability such as tachycardia, labile blood pressure, or hyperthermia; and neurologic abnormalities such as hyperreflexia, incoordination, or rigidity.
- The onset of symptoms generally occurs within several hours to a few days of concomitant use but may occur later, particularly after dose increases.
- Discontinue opioid treatment and/or use of the concomitant serotonergic drug if serotonin syndrome is suspected.
- Counsel patients about the symptoms of serotonin syndrome and advise them to seek medical attention immediately if symptoms develop.
- Instruct patients to inform their health care professionals if they are taking or plan to take serotonergic drugs.

Adrenal insufficiency

- Cases of adrenal insufficiency have been reported with opioid use.
- Presentation of adrenal insufficiency may include nonspecific symptoms and signs, including nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure.
- If adrenal insufficiency is suspected, confirm with diagnostic testing as soon as possible. The patient should be treated with physiologic replacement doses of corticosteroids and weaned off of the opioid to allow adrenal function to recover.
- If the opioid can be discontinued, follow-up assessment of adrenal function should be performed to determine if treatment with corticosteroids can be discontinued.
- Other opioids may be tried as some cases reported use of a different opioid without recurrence of adrenal insufficiency.
- The information available does not identify any particular opioids as being more likely to be associated with adrenal insufficiency.

Androgen deficiency

- Chronic use of opioids may influence the hypothalamic-pituitary-gonadal axis, leading to androgen deficiency that may manifest as low libido, impotence, erectile dysfunction, amenorrhea, or infertility.
- The causal role of opioids in the clinical syndrome of hypogonadism is unknown because the various medical, physical, lifestyle, and psychological stressors that may influence gonadal hormone levels have not been adequately controlled in studies conducted to date.
- Patients presenting with symptoms or signs of androgen deficiency should undergo laboratory evaluation.

General information

- Encourage patients to read the information leaflets or Medication Guides that come with their filled prescription(s).
- Report adverse events involving opioids or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Data Summary

FDA investigated several safety issues associated with the class of opioid pain medicines:

- Serotonin syndrome
- Adrenal insufficiency
- Androgen deficiency

Serotonin syndrome

A search of the FDA Adverse Event Reporting System (FAERS) database for the period January 1, 1969, to June 12, 2013, identified 43 cases of serotonin syndrome in which opioids were used concomitantly with other serotonergic drugs. The review excluded meperidine, tramadol, and tapentadol, which were already labeled for the risk of serotonin syndrome at the time of the review. The most commonly reported opioids associated with serotonin syndrome were fentanyl (n=28), oxycodone (n=7), and methadone (n=5). Other reported opioids included hydromorphone, morphine, alfentanil/remifentanil/sufentanil, hydrocodone, naltrexone, and pentazocine. Although there were no reports of serotonin syndrome with an opioid used alone, five cases reported that serotonin syndrome occurred with the use of two or more opioids concurrently. All of these five cases reported use of fentanyl along with at least one other opioid [oxycodone (n=4), morphine (n=1), hydromorphone (n=1), and hydrocodone (n=1)].

Adrenal insufficiency

A search of FAERS for the period January 1, 1969, to February 5, 2014, identified 37 cases of adrenal insufficiency reported with the use of opioids. Twenty-seven cases reported opioid monotherapy, and 10 reported use of more than one opioid at the same time. The most commonly reported opioids associated with adrenal insufficiency were fentanyl (n=10) and oxycodone (n=10), followed by buprenorphine or

buprenorphine/naloxone (n=7), hydromorphone (n=6), and tramadol (n=4). When reported, the time to onset of adrenal insufficiency after the start of opioid therapy ranged from within 1 day to more than 1 year; however, many of the cases reported adrenal insufficiency after at least 1 month of use. Many of the patients were hospitalized. Of the 37 cases, 21 described that the patients received corticosteroid treatment. Sixteen cases reported discontinuing or reducing the dose of the opioid. Of the 16, nine of these patients improved, three had ongoing symptoms, and four did not report an outcome. Some patients experienced a relief in symptoms when they were switched from one opioid to another.

Androgen deficiency

We reviewed the medical literature to evaluate the association between opioids and androgen deficiency.¹⁻²¹ A range of studies in a variety of settings demonstrated decreased gonadal hormones in men and women taking long-term opioids. However, most of the studies were descriptive prevalence studies that did not include baseline values for the hormone levels, and there was a lack of comparability between the opioid-treated groups and control groups regarding medical, physical, lifestyle, and psychological factors that may influence gonadal hormone levels. Due to limitations of the studies, it is unclear whether the low gonadal hormone levels and associated symptoms and signs in men and women could be attributed to long-term opioid use or to other factors such as the patient's underlying medical condition warranting opioid treatment; physical, mental, or life stressors; weight changes; or concomitant medication or supplement use.

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**UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK**

In re:

**PURDUE PHARMA L.P., *et al.*,
Debtors.¹**

Chapter 11

Case No. 19-23649 (RDD)

(Jointly Administered)

**ORDER DENYING MOTION FOR SUMMARY JUDGMENT AND PAYMENT OF
CLAIM**

Upon the motion [Dkt. No. 3191] (the “**Motion**”) of Amanda Morales, pro se, couched as a motion for summary judgment and requesting that this Court allow in full her unliquidated and contingent proof of claim filed in these cases (the “**Claim**”)² against the estates of the debtors and debtors in possession herein (the “**Debtors**”) and, to the extent the Claim is allowed, direct that it be paid now, before the confirmation and effective date of a chapter 11 plan in these cases; and upon the Debtors’ objection to the Motion and Ms. Morales’ reply, including the exhibits thereto; and the Court having jurisdiction to consider the matters raised in the Motion pursuant to 28 U.S.C. §§ 157(a)-(b) and 1334(b) and the Amended Standing Order of Reference M-431, dated January 31, 2012 (Preska, C.J.), as a core proceeding under 28 U.S.C. § 157(b); and venue being proper before the Court pursuant to 28 U.S.C. §§ 1408 and 1409; and upon the record of

¹ The Debtors in these cases, along with the last four digits of each Debtor’s registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717), and SVC Pharma Inc. (4014). The Debtors’ corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

² The Claim number is 619945.

the hearing held by the Court on the Motion on August 16, 2021; and, after due deliberation, and for the reasons stated by the Court in its bench ruling at the hearing, the Court having determined that the payment in full of the Claim but not all claims similarly situated to the Claim before the confirmation and effective date of a chapter 11 plan in these cases would be premature and violate the fundamental Bankruptcy Code principles of similar treatment of similar claims and the resolution and treatment of general unsecured claims under a chapter 11 plan and is not warranted by any exception to such principles; now, therefore, IT IS HEREBY ORDERED THAT:

1. The Motion is denied without prejudice to the merits of the Claim,
2. Except as expressly set forth in this Order, nothing contained herein shall be an admission or waiver of the substantive or procedural rights, remedies, claims, or defenses of, or otherwise prejudice the rights of any of the parties in these chapter 11 cases, whether at law or equity, with respect to the Claim, including Ms. Morales' right to have the Claim determined and paid at a future date and any objections thereto on the merits of the Claim.

Dated: August 18, 2021
White Plains, New York

/s/Robert D. Drain

THE HONORABLE ROBERT D. DRAIN
UNITED STATES BANKRUPTCY JUDGE

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 16 day of January, 2024, a copy
of the document(s) entitled Complaint
was/were mailed, postage prepaid to:

Title of Document(s) Complaint

Opposing Party or His/Her Attorney

Address

City

State

Zip

Date

Signature

Preis, Anik

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1/16/2024

Jamanda Hooks